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U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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and MCKESSON CORPORATION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

WHA

TERRI RANDALL, an individual,
Plaintiff,

v.

ORTHO-MCNEIL PHARMACEUTICAL,
INC., a Delaware Corporation;
MCKESSON CORP. and DOES 1-500,
inclusive,
Defendants.

Case No. 07 3424
DEFENDANTS' ANSWER TO
PLAINTIFF'S COMPLAINT; DEMAND
FOR JURY TRIAL

Defendants Ortho-McNeil Pharmaceutical, Inc. ("OMP") and McKesson Corporation ("McKesson"), (collectively "Defendants"), by and through counsel, hereby respond to the allegations set forth in Plaintiff's Complaint as follows:

ANSWER TO INTRODUCTION

1. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 1 of Plaintiff's Complaint. Defendants assert that no successor-in-interest declaration has been filed as required by California Code of Civil Procedure Section 377.32.

2. Defendants are without knowledge or information sufficient to form a belief as to Plaintiff's allegations that decedent used ORTHO EVRA®. Defendants

COPY

1 deny the remaining allegations contained in paragraph 2 of Plaintiff's Complaint.

2 3. Defendants admit that OMP manufactured, advertised, promoted, marketed,
3 sold and distributed ORTHO EVRA®. Defendants deny the remaining allegations
4 contained in paragraph 3 of Plaintiff's Complaint.

5 4. Defendants admit that McKesson is a non-exclusive distributor of ORTHO
6 EVRA® and has its principal place of business in San Francisco, California. Defendants
7 deny the remaining allegations contained in paragraph 4 of Plaintiff's Complaint.

8 5. Defendants admit that on the ORTHO EVRA® Web site, it states that:
9 "The transdermal -- or 'through the skin' -- weekly birth control patch prevents
10 pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl
11 estradiol (progestin and estrogen, respectively) through the skin and into the
12 bloodstream." Defendants admit that the FDA approved the use of ORTHO EVRA® for
13 the prevention of pregnancy in November 2001. Defendants further admit that the FDA's
14 publications state what they state. Defendants deny the remaining allegations contained
15 in paragraph 5 of Plaintiff's Complaint.

16 ANSWER TO JURISDICTION AND VENUE

17 6. Paragraph 6 of Plaintiff's Complaint contains legal conclusions to which no
18 response is required.

19 7. Defendants admit that OMP is a Delaware corporation with its principal
20 place of business in New Jersey, and McKesson is a Delaware corporation with its
21 principal place of business in California. Defendants deny the remaining allegations
22 contained in paragraph 7 of Plaintiff's Complaint.

23 8. Defendants admit that McKesson has its principal place of business in San
24 Francisco, California. Defendants deny the remaining allegations contained in paragraph
25 8 of Plaintiff's Complaint.

26 9. Defendants admit that McKesson has its principal place of business in San
27 Francisco, California. Defendants deny the remaining allegations contained in paragraph
28 9 of Plaintiff's Complaint.

10. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 10 of Plaintiff's Complaint.

ANSWER TO PLAINTIFF

11. Defendants are without knowledge or information sufficient to form a belief as to where Plaintiff resides or Plaintiff's allegations that decedent was prescribed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 11 of Plaintiff's Complaint.

ANSWER TO DEFENDANTS

12. Defendants admit that OMP is a Delaware corporation with its principal place of business in New Jersey. Defendants deny the remaining allegations contained in paragraph 12 of Plaintiff's Complaint.

13. Defendants admit that OMP conducts business in California. Defendants deny the remaining allegations contained in paragraph 13 of Plaintiff's Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 14 of Plaintiff's Complaint, and therefore these allegations are denied.

15. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 15 of Plaintiff's Complaint, and therefore these allegations are denied.

16. Defendants admit that OMP manufactured, marketed, promoted, sold and distributed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 16 of Plaintiff's Complaint.

17. Defendants admit that McKesson is a Delaware corporation with its principal place of business in San Francisco, California. Defendants further admit that McKesson conducts business in California. Defendants deny the remaining allegations contained in paragraph 17 of Plaintiff's Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 18 of Plaintiff's Complaint, and

1 therefore these allegations are denied.

2 19. Defendants are without knowledge or information sufficient to form a
3 belief as to the allegations contained in paragraph 19 of Plaintiff's Complaint, and
4 therefore these allegations are denied.

5 20. Defendants admit that McKesson is a non-exclusive distributor of ORTHO
6 EVRA®. Defendants deny the remaining allegations contained in paragraph 20 of
7 Plaintiff's Complaint.

8 21. Defendants are without knowledge or information sufficient to form a
9 belief as to the allegations contained in paragraph 21 of Plaintiff's Complaint.

10 22. Defendants are without knowledge or information sufficient to form a
11 belief as to the allegations contained in paragraph 22 of Plaintiff's Complaint.

12 23. To the extent that paragraph 23 of Plaintiff's Complaint alleges improper
13 conduct on the part of Defendants, such allegations are denied.

14 24. To the extent that paragraph 24 of Plaintiff's Complaint alleges improper
15 conduct on the part of Defendants, such allegations are denied.

16 **ANSWER TO GENERAL ALLEGATIONS**

17 25. OMP admits that on the Ortho-McNeil Pharmaceutical, Inc. Web site, it
18 states that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in
19 women's health care. Ortho-McNeil offers the broadest range of prescription birth control
20 options..." OMP further admits that it manufactures and sells ORTHO EVRA®, the first
21 combination transdermal contraceptive patch. Defendants deny the remaining allegations
22 contained in paragraph 25 of Plaintiff's Complaint.

23 26. OMP admits that ORTHO EVRA® is the first and only once-a-week birth
24 control patch. OMP further admits that on the ORTHO EVRA® Web site, it states that:
25 "The transdermal -- or 'through the skin' -- weekly birth control patch prevents
26 pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl
27 estradiol (progestin and estrogen, respectively) through the skin and into the
28 bloodstream." Defendants deny the remaining allegations contained in paragraph 26 of

1 Plaintiff's Complaint.

2 27. Defendants admit that a New Drug Application ("NDA") was filed for
3 ORTHO EVRA®, denoted as 21-180, with the FDA in December 2000. Defendants
4 further admit that the FDA Medical Officer's Review for ORTHO EVRA® states what it
5 states. Defendants deny the remaining allegations contained in paragraph 27 of
6 Plaintiff's Complaint.

7 28. Defendants admit that the FDA approved the use of ORTHO EVRA® for
8 the prevention of pregnancy in November 2001. Defendants deny the remaining
9 allegations contained in paragraph 28 of Plaintiff's Complaint.

10 29. Defendants admit that as with all prescription medicine, adverse events are
11 reported to the FDA by a variety of people and entities. Defendants deny the remaining
12 allegations contained in paragraph 29 of Plaintiff's Complaint.

13 30. Defendants admit that the FDA's publications state what they state.
14 Defendants deny the remaining allegations contained in paragraph 30 of Plaintiff's
15 Complaint.

16 31. Defendants admit that the November 2005 package insert for ORTHO
17 EVRA® states what it states. To the extent that paragraph 31 of Plaintiff's Complaint
18 alleges improper conduct on the part of Defendants, such allegations are denied.

19 32. Defendant OMP admits that ORTHO EVRA® is the first and only once-a-
20 week birth control patch. Defendants deny the remaining allegations contained in
21 paragraph 32 of Plaintiff's Complaint.

22 33. Defendants deny the allegations contained in paragraph 33 of Plaintiff's
23 Complaint.

24 34. Defendants admit that the package insert for ORTHO EVRA® states what
25 it states. To the extent that paragraph 34 of Plaintiff's Complaint alleges improper
26 conduct on the part of Defendants, such allegations are denied.

27 35. Defendants deny the allegations contained in paragraph 35 of Plaintiff's
28 Complaint.

36. Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in paragraph 36 of Plaintiff's Complaint to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties.

37. Defendants deny the allegations contained in paragraph 37 of Plaintiff's Complaint.

38. Defendants deny the allegations contained in paragraph 38 of Plaintiff's Complaint.

39. Defendants deny the allegations contained in paragraph 39 of Plaintiff's Complaint.

40. Defendants deny the allegations contained in paragraph 40 of Plaintiff's Complaint.

ANSWER TO FRAUDULENT CONCEALMENT

41. Defendants deny the allegations contained in paragraph 41 of Plaintiff's Complaint.

42. Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in paragraph 42 of Plaintiff's Complaint to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties, and deny the remaining allegations contained in this paragraph.

ANSWER TO FIRST CAUSE OF ACTION

NEGLIGENCE

43. Defendants repeat their answers to the allegations of paragraphs 1 through 42 of Plaintiff's Complaint as if set forth at length herein.

44. Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in paragraph 44 of the First Cause of Action of Plaintiff's Complaint to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties.

1 45. Defendants deny the allegations contained in paragraph 45 of the First
2 Cause of Action of Plaintiff's Complaint.

3 46. Defendants deny the allegations contained in paragraph 46 of the First
4 Cause of Action of Plaintiff's Complaint.

5 47. Defendants deny the allegations contained in paragraph 47 of the First
6 Cause of Action of Plaintiff's Complaint.

7 48. Defendants deny the allegations contained in paragraph 48 of the First
8 Cause of Action of Plaintiff's Complaint.

9 49. Defendants deny the allegations contained in paragraph 49 of the First
10 Cause of Action of Plaintiff's Complaint.

11 50. Defendants deny the allegations contained in paragraph 50 of the First
12 Cause of Action of Plaintiff's Complaint.

13 51. Defendants deny the allegation that ORTHO EVRA® is defective, and
14 deny the remaining allegations contained in paragraph 51 of the First Cause of Action of
15 Plaintiff's Complaint.

16 52. Defendants deny the allegations contained in paragraph 52 of the First
17 Cause of Action of Plaintiff's Complaint.

18 53. Defendants deny the allegations contained in paragraph 53 of the First
19 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
20 the unnumbered paragraph following paragraph 53.

21 **ANSWER TO SECOND CAUSE OF ACTION**

22 **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

23 54. Defendants repeat their answers to the allegations of paragraphs 1 through
24 53 of Plaintiff's Complaint as if set forth at length herein.

25 55. Defendants admit that OMP manufactures and supplies ORTHO EVRA®.
26 Defendants deny the remaining allegations contained in paragraph 55 of the Second
27 Cause of Action of Plaintiff's Complaint.

28 56. Defendants admit that OMP manufactures and supplies ORTHO EVRA®.

1 Defendants deny the remaining allegations contained in paragraph 56 of the Second
2 Cause of Action of Plaintiff's Complaint.

3 57. Defendants deny the allegations contained in paragraph 57 of the Second
4 Cause of Action of Plaintiff's Complaint.

5 58. Defendants deny the allegation that ORTHO EVRA® is defective, and
6 deny the remaining allegations contained in paragraph 58 of the Second Cause of Action
7 of Plaintiff's Complaint.

8 59. Defendants deny the allegation that ORTHO EVRA® is defective, and
9 deny the remaining allegations contained in paragraph 59 of the Second Cause of Action
10 of Plaintiff's Complaint.

11 60. Defendants deny the allegations contained in paragraph 60 of the Second
12 Cause of Action of Plaintiff's Complaint.

13 61. Defendants deny the allegation that ORTHO EVRA® is defective, and
14 deny the remaining allegations contained in paragraph 61 of the Second Cause of Action
15 of Plaintiff's Complaint.

16 62. Defendants deny the allegations contained in paragraph 62 of the Second
17 Cause of Action of Plaintiff's Complaint.

18 63. Defendants deny the allegations contained in paragraph 63 of the Second
19 Cause of Action of Plaintiff's Complaint.

20 64. Defendants deny the allegations contained in paragraph 64 of the Second
21 Cause of Action of Plaintiff's Complaint.

22 65. Defendants deny the allegations contained in paragraph 65 of the Second
23 Cause of Action of Plaintiff's Complaint.

24 66. Defendants deny the allegations contained in paragraph 66 of the Second
25 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
26 the unnumbered paragraph following paragraph 66.

**ANSWER TO THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY**

67. Defendants repeat their answers to the allegations of paragraphs 1 through 66 of Plaintiff's Complaint as if set forth at length herein.

68. Defendants deny the allegations contained in paragraph 68 of the Third Cause of Action of Plaintiff's Complaint.

69. Defendants deny the allegations contained in paragraph 69 of the Third Cause of Action of Plaintiff's Complaint.

70. Defendants deny the allegations contained in paragraph 70 of the Third Cause of Action of Plaintiff's Complaint.

71. Defendants deny the allegations contained in paragraph 71 of the Third Cause of Action of Plaintiff's Complaint.

72. Defendants deny the allegations contained in paragraph 72 of the Third Cause of Action of Plaintiff's Complaint.

73. Defendants deny the allegations contained in paragraph 73 of the Third Cause of Action of Plaintiff's Complaint.

74. Defendants deny the allegations contained in paragraph 74 of the Third Cause of Action of Plaintiff's Complaint.

75. Defendants deny the allegations contained in paragraph 75 of the Third Cause of Action of Plaintiff's Complaint.

76. Defendants deny the allegations contained in paragraph 76 of the Third Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 76.

**ANSWER TO FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY**

77. Defendants repeat their answers to the allegations of paragraphs 1 through 76 of Plaintiff's Complaint as if set forth at length herein.

78. Defendants admit that OMP marketed, sold and distributed ORTHO

1 EVRA®, which is used for the prevention of pregnancy. Defendants further admit that
2 McKesson is a non-exclusive distributor of ORTHO EVRA®, and deny that McKesson
3 marketed or sold ORTHO EVRA®. The remainder of paragraph 78 of the Fourth Cause
4 of Action of Plaintiff's Complaint contains a legal conclusion to which no response is
5 required.

6 79. Paragraph 79 of the Fourth Cause of Action of Plaintiff's Complaint
7 contains legal conclusions to which no response is required.

8 80. Defendants are without knowledge or information sufficient to form a
9 belief as to the allegations contained in paragraph 80 of the Fourth Cause of Action of
10 Plaintiff's Complaint, and therefore these allegations are denied.

11 81. Defendants deny the allegations contained in paragraph 81 of the Fourth
12 Cause of Action of Plaintiff's Complaint.

13 82. Defendants deny the allegations contained in paragraph 82 of the Fourth
14 Cause of Action of Plaintiff's Complaint.

15 83. Defendants deny the allegations contained in paragraph 83 of the Fourth
16 Cause of Action of Plaintiff's Complaint.

17 84. Defendants deny the allegations contained in paragraph 84 of the Fourth
18 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
19 the unnumbered paragraph following paragraph 84.

20 **ANSWER TO FIFTH CAUSE OF ACTION**

21 **NEGLIGENT MISREPRESENTATION**

22 85. Defendants repeat their answers to the allegations of paragraphs 1 through
23 84 of Plaintiff's Complaint as if set forth at length herein.

24 86. Defendants admit that OMP manufactures, markets, promotes, and sells
25 ORTHO EVRA®. Defendants further state that they were subject only to those duties
26 imposed by applicable law, and deny the allegations contained in this paragraph to the
27 extent they suggest any different or greater duties. Defendants further deny that they
28 failed to abide by any applicable legal duties, and deny the remaining allegations

1 contained in paragraph 86 of the Fifth Cause of Action of Plaintiff's Complaint.

2 87. Defendants deny the allegations contained in paragraph 87 of the Fifth
3 Cause of Action of Plaintiff's Complaint.

4 88. Defendants deny the allegations contained in paragraph 88 of the Fifth
5 Cause of Action of Plaintiff's Complaint.

6 89. Defendants deny the allegations contained in paragraph 89 of the Fifth
7 Cause of Action of Plaintiff's Complaint.

8 90. Defendants deny the allegations contained in paragraph 90 of the Fifth
9 Cause of Action of Plaintiff's Complaint.

10 91. Defendants deny the allegations contained in paragraph 91 of the Fifth
11 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
12 the unnumbered paragraph following paragraph 91.

13 ANSWER TO SIXTH CAUSE OF ACTION

14 FRAUD

15 92. Defendants repeat their answers to the allegations of paragraphs 1 through
16 91 of Plaintiff's Complaint as if set forth at length herein.

17 93. Defendants admit that OMP manufactures, markets, promotes, and sells
18 ORTHO EVRA®. Defendants further state that they were subject only to those duties
19 imposed by applicable law, and deny the allegations contained in this paragraph to the
20 extent they suggest any different or greater duties. Defendants further deny that they
21 failed to abide by any applicable legal duties, and deny the remaining allegations
22 contained in paragraph 93 of the Sixth Cause of Action of Plaintiff's Complaint.

23 94. Defendants deny the allegations contained in paragraph 94 of the Sixth
24 Cause of Action of Plaintiff's Complaint.

25 95. Defendants deny the allegations contained in paragraph 95 of the Sixth
26 Cause of Action of Plaintiff's Complaint.

27 96. Defendants deny the allegations contained in paragraph 96 of the Sixth
28 Cause of Action of Plaintiff's Complaint.

1 97. Defendants deny the allegations contained in paragraph 97 of the Sixth
2 Cause of Action of Plaintiff's Complaint.

3 98. Defendants deny the allegations contained in paragraph 98 of the Sixth
4 Cause of Action of Plaintiff's Complaint.

5 99. Defendants deny the allegations contained in paragraph 99 of the Sixth
6 Cause of Action of Plaintiff's Complaint.

7 100. Defendants deny the allegations contained in paragraph 100 of the Sixth
8 Cause of Action of Plaintiff's Complaint.

9 101. Defendants are without knowledge or information sufficient to form a
10 belief as to the state of mind of Plaintiff or the decedent. Defendants deny the remaining
11 allegations contained in paragraph 101 of the Sixth Cause of Action of Plaintiff's
12 Complaint.

13 102. Defendants deny the allegations contained in paragraph 102 of the Sixth
14 Cause of Action of Plaintiff's Complaint.

15 103. Defendants deny the allegations contained in paragraph 103 of the Sixth
16 Cause of Action of Plaintiff's Complaint.

17 104. Defendants deny the allegations contained in paragraph 104 of the Sixth
18 Cause of Action of Plaintiff's Complaint.

19 105. Defendants deny the allegations contained in paragraph 105 of the Sixth
20 Cause of Action of Plaintiff's Complaint and controvert the prayers for relief set forth in
21 the unnumbered paragraph following paragraph 105.

22 **ANSWER TO SEVENTH CAUSE OF ACTION**

23 **WRONGFUL DEATH**

24 106. Defendants repeat their answers to the allegations of paragraphs 1 through
25 105 of Plaintiff's Complaint as if set forth at length herein.

26 107. Defendants deny the allegations contained in paragraph 107 of the Sixth
27 Cause of Action of Plaintiff's Complaint.

28 108. To the extent that this paragraph of Plaintiff's Complaint alleges improper

1 conduct on the part of Defendants, such allegations are denied. Defendants are without
 2 knowledge or information sufficient to form a belief as to the remaining allegations
 3 contained in paragraph 108 of Plaintiff's Complaint and assert that no successor-in-
 4 interest declaration has been filed as required by California Code of Civil Procedure
 5 Section 377.32.

6 109. Defendants deny the allegations contained in paragraph 109 of the Sixth
 7 Cause of Action of Plaintiff's Complaint.

8 110. Defendants deny the allegations contained in paragraph 110 of the Sixth
 9 Cause of Action of Plaintiff's Complaint.

10 **FIRST AFFIRMATIVE DEFENSE**

11 Plaintiff's Complaint fails to state a claim against Defendants upon which relief
 12 may be granted.

13 **SECOND AFFIRMATIVE DEFENSE**

14 Plaintiff's claims are barred by the applicable statute of limitations, statute of
 15 repose and/or by the equitable doctrines of laches and estoppel.

16 **THIRD AFFIRMATIVE DEFENSE**

17 Plaintiff's claims are barred by the doctrines of informed consent, release and
 18 waiver.

19 **FOURTH AFFIRMATIVE DEFENSE**

20 Plaintiff's claims are barred because the alleged damages, if any are proven, were
 21 not proximately caused by any act or omission of any of the Defendants.

22 **FIFTH AFFIRMATIVE DEFENSE**

23 If Plaintiff and/or the decedent suffered any of the injuries, losses and damages
 24 alleged, then said injuries, losses and damages were a direct and proximate result of a
 25 responsible, superseding, and/or intervening cause.

26 **SIXTH AFFIRMATIVE DEFENSE**

27 Defendants state that if Plaintiff and/or the decedent has suffered any of the
 28 injuries, losses and damages alleged, then said injuries, losses and damages were due to

1 an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by
 2 an unforeseeable illness, unavoidable accident or preexisting condition, without any
 3 negligence and culpable conduct by Defendants.

4 **SEVENTH AFFIRMATIVE DEFENSE**

5 Plaintiff and/or the decedent's injuries and damages, if any, were caused in whole
 6 or in part by the acts (wrongful or otherwise), negligence, sole fault, misuse, abuse,
 7 modification, alteration, omission or fault of one or more persons or entities over whom
 8 Defendants exercised no control and for whom Defendants are not legally responsible,
 9 including, without limitation, Plaintiff and/or the decedent.

10 **EIGHTH AFFIRMATIVE DEFENSE**

11 Plaintiff and/or the decedent failed to exercise reasonable care and diligence to
 12 mitigate injuries and damages, if any.

13 **NINTH AFFIRMATIVE DEFENSE**

14 Plaintiff's claims are barred by the "state of the art" and "state of scientific
 15 knowledge" defenses.

16 **TENTH AFFIRMATIVE DEFENSE**

17 Plaintiff's claims are barred by the Learned Intermediary Doctrine.

18 **ELEVENTH AFFIRMATIVE DEFENSE**

19 The product at issue in this case falls under the auspices of the Food, Drug and
 20 Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration,
 21 and therefore, Federal law preempts Plaintiff's claims. *See*, 21 U.S.C. §301 *et. seq.* *See*
 22 *also*, 71 Fed. Reg. 3922 (January 24, 2006).

23 **TWELFTH AFFIRMATIVE DEFENSE**

24 Defendants did not make to Plaintiff and/or the decedent nor did they breach any
 25 express or implied warranties and/or breach any warranties created by law. To the extent
 26 that Plaintiff relies on any theory of breach of warranty, such claims are barred by
 27 applicable law, and for lack of privity with Defendants and/or for failure of Plaintiff
 28 and/or the decedent and/or their respective representatives, to give timely notice to

1 Defendants of any alleged breach of warranty. Plaintiff and/or the decedent did not rely
 2 on any alleged warranty. Defendants further specifically plead as to any breach of
 3 warranty claim all affirmative defenses under the Uniform Commercial Code existing
 4 and which may arise in the future, as enacted in the State of California, and any other
 5 state whose law is deemed to apply in this case.

6 **THIRTEENTH AFFIRMATIVE DEFENSE**

7 Plaintiff's claims are barred by comments j and k to Section 402A of the
 8 Restatement (Second) of Torts.

9 **FOURTEENTH AFFIRMATIVE DEFENSE**

10 Plaintiff's claims of product defects are barred by Section 2, 4, and 6(c) and (d) of
 11 the Restatement (Third) of Torts: Products Liability.

12 **FIFTEENTH AFFIRMATIVE DEFENSE**

13 Plaintiff's product liability claims are barred because the benefits of the relevant
 14 product outweighed its risks.

15 **SIXTEENTH AFFIRMATIVE DEFENSE**

16 Plaintiff's claims are barred in whole or part because the product at issue was at all
 17 times properly prepared, packaged, and distributed, and was not defective or
 18 unreasonably dangerous.

19 **SEVENTEENTH AFFIRMATIVE DEFENSE**

20 Any imposition of punitive damages in this case against Defendants is barred to
 21 the extent that the manner in which such punitive damages are calculated violates the
 22 Constitution of the United States or the Constitution of the State of California.

23 **EIGHTEENTH AFFIRMATIVE DEFENSE**

24 Any award of punitive damages in this case against Defendants is barred to the
 25 extent that the amount of such an award violates the Constitution of the United States or
 26 the Constitution of the State of California.

27 **NINETEENTH AFFIRMATIVE DEFENSE**

28 Plaintiff has failed to plead fraud with specificity.

TWENTIETH AFFIRMATIVE DEFENSE

Defendants are entitled to a setoff for all amounts paid, payable by or available from collateral sources.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Venue is improper in this court.

TWENTY-SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a cause of action against Defendants because there is no private right of action under the applicable federal law. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to *Buckman v. Plaintiff's Legal Community*, 531 U.S. 341 (2001).

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff and/or the decedent knowingly and voluntarily assumed any and all risks associated with the use of the product at issue, barring in whole or in part the damages Plaintiff seeks to recover.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

In the event Defendants, or any of them, are held liable to Plaintiff, which liability is expressly denied, or a settlement of judgment against Defendants, or any of them, is reached, Defendants request an apportionment of fault be made as permitted by *Li v. Yellow Cab Company*, 13 Cal.3d 804 (1975) and *American Motorcycle Association v. Superior Court*, 20 Cal.3d 578 (1987) and a judgment and declaration of indemnification and contribution be entered against all other persons and entities in accordance with that apportionment of fault.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

The amount of any award on behalf of Plaintiff for non-economic loss must be allocated according to the provisions of California Civil Code Section 1431.2 ("Proposition 51").

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff lacks standing to bring this action as she is not the personal representative

1 or successor-in-interest of the decedent and/or because no successor-in-interest
2 declaration has been filed as required by California Code of Civil Procedure Section
3 377.32.

4 **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

5 Plaintiff's claims for pain, suffering, and disfigurement, if any, are barred by
6 California Code of Civil Procedure Sections 377.34 and 377.61.

7 **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

8 Defendants specifically reserve the right to amend their Answer by adding
9 defenses, counterclaims, cross claims or by instituting third party actions as additional
10 facts are obtained.


11 WHEREFORE, having fully answered, Defendants specifically controvert
12 Plaintiff's Prayer for Relief including Paragraphs (1)-(6).

13 **JURY DEMAND**

14 Defendants hereby demand a trial by jury of all the facts and issues in this case
15 pursuant to Federal Rule of Civil Procedure 38(b).

16
17 Dated: June 29, 2007

DRINKER BIDDLE & REATH LLP

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20 BRENDAN N. BUONAIUTO

21 Attorneys for Defendants

22 ORTHO-MCNEIL PHARMACEUTICAL,
23 INC. and MCKESSON CORPORATION
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